

### **Will the 2009 H1N1 influenza vaccines be safe?**

The 2009 H1N1 flu vaccines are being produced using the same technology as seasonal flu vaccines so we expect it to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects are mild, such as soreness, redness, tenderness or swelling where the shot was given. The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and we will work with state and local health officials to investigate any unusual events.

### **Are there any side effects to the 2009 H1N1 flu vaccine?**

CDC expects that side effects following vaccination with the 2009 H1N1 flu vaccine to be rare. If side effects occur, they will likely be similar to those from seasonal flu vaccine. Mild problems that may be experienced include soreness, redness, or swelling where the shot was given, fainting (mainly adolescents), headache, muscle aches, fever and nausea. If these problems occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot is given.

### **Are there some people who should not receive this vaccine?**

People who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

### **How will the 2009 H1N1 flu vaccines be monitored for safety?**

The CDC and FDA closely monitor the safety of seasonal flu and other vaccines licensed for use in the United States in cooperation with state and local health departments, healthcare providers and other partners.

The purpose of vaccine safety monitoring is timely identification of clinically significant adverse events or side effects following immunization that may be of public health concern. Note that adverse events, or possible side effects, following immunization may or may not be related to the vaccine given.

CDC and its partners will use multiple systems to monitor the safety of 2009 H1N1 flu vaccine. Two of the primary systems that will be used to monitor the safety of these vaccines after they are in widespread use are: the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA and the Vaccine Safety Data link (VSD) Project. These monitoring systems are in place and used for all vaccines given in the United States.

### **Will the 2009 H1N1 vaccine that is currently recommended contain adjuvant?**

None of the currently available forms of the 2009 H1N1 flu vaccines licensed (approved) for use in the United States will contain an adjuvant.

### **Will the benefits of the 2009 H1N1 flu vaccines outweigh the risks?**

CDC and FDA believe that the benefits of vaccination with the 2009 H1N1 flu vaccine far outweigh the risks. Currently the 2009 H1N1 flu virus (sometimes called "swine flu") seems to be causing serious health outcomes for:

1. Healthy young people from birth through age 24;
2. Pregnant women; and
3. Adults 25 to 64 who have underlying medical conditions.

Seasonal flu vaccines are highly effective in preventing flu disease. The expectation is that a vaccine against 2009 H1N1 flu would probably work in a similar fashion as the seasonal flu vaccines. Vaccination is the best way to prevent flu infection and its complications.

## **Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine?**

Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Infection with the bacterium [Campylobacter jejuni](#), which can cause diarrhea, is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

In 1976, there was a small risk of GBS following flu (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal flu vaccine. FDA and CDC will be closely monitoring reports of serious problems following the 2009 H1N1 flu vaccines, including GBS.

## **Will the 2009 H1N1 flu vaccine contain thimerosal?**

The 2009 H1N1 flu vaccines that FDA is licensing will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal flu vaccine also contain thimerosal to prevent potential contamination after the vial is opened. There will also be thimerosal-free vaccine available in the form of single dose injections and single dose intranasal (given through the nose).

## **Is the live virus vaccine (intranasal) safe for health care workers (HCW)?**

Yes the live attenuated influenza vaccine (LAIV) is safe for healthy non-pregnant people between the ages of 2 and 49 years old and those for whom they care.

1. In this group, the only people that should not receive LAIV are those who work with the severely immunosuppressed. That includes patients who require special living conditions to reduce the risk of infection.
2. All other people can receive a LAIV and return to work immediately without posing a risk to those for whom they care, even those who work with very young children (including newborn infants) or pregnant women.

There is no risk of developing the flu from receiving either of these live virus vaccines. NO cases of flu have been linked to receiving LAIV.

Reference: CDC. Prevention and Control of Seasonal Influenza with Vaccines, Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR 2009;58(RR08):1-52).

<http://www.cdc.gov/mmwr/PDF/rr/rr5808.pdf>.

## **What is the best source of information for 2009 H1N1 flu vaccine safety?**

In addition to talking openly with your healthcare providers, CDC also encourages you to stay informed by checking the following Web sites often for the most up-to-date news and information: [www.cdc.gov/H1N1flu](http://www.cdc.gov/H1N1flu) and [www.flu.gov](http://www.flu.gov).